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K033365  
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## Section 2 Summary

### 510(k) Summary of Safety and Effectiveness

Date: October 20, 2003

Submitter: GE Medical Systems *Information Technologies*  
8200 West Tower Avenue  
Milwaukee, WI 53223 USA

Contact Person: Diana M. Thorson  
Regulatory Affairs Specialist  
GE Medical Systems *Information Technologies*  
Phone: 714-247-4135  
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Device: Trade Name: ApexPro FH Telemetry System

Common/Usual Name: Telemetry Monitoring System

Classification Names:

21 CFR 870.1025 Detector and Alarm, Arrhythmia

21 CFR 870.2910 Transmitters & Receivers, Physiological Signal, Radio Frequency

Predicate Device: K032369 ApexPro Telemetry System

Device Description: The ApexPro FH Telemetry System is composed of six major components:

- Accessories to the patient worn acquisition transceivers
- The patient worn data acquisition transceivers
- The transceiver access points with antenna
- The network infrastructure
- A computer platform running the ApexPro Telemetry Application
- A computer platform running a central station application (which may be the same computer platform running the ApexPro Telemetry Application)

Intended Use: The ApexPro FH Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro FH Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure, non-invasive temperature and SpO<sub>2</sub>. The ApexPro FH Telemetry System is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro FH is also intended to provide physiologic data over the Unity network to clinical information systems for display.

Technology: The ApexPro FH employs the same functional technology as the predicate devices. The system architecture has taken advantage of improvements in signal processing technology as well as advances in RF component technologies to improve performance and level of integration.

Test Summary: The ApexPro FH complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the ApexPro FH System is as safe, as effective, and performs as well as the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**NOV - 6 2003**

GE Medical Systems Information Technologies  
c/o Ms. Diane M. Thorson  
Corporate Regulatory Affairs  
8200 West Tower Avenue  
Milwaukee, WI 53223

Re: K033365

Trade Name: ApexPro FH Telemetry System  
Regulation Number: 21 CFR 870.1025  
Regulation Name: Arrhythmia Detector and Alarm  
Regulatory Class: Class II (three)  
Product Code: MHX  
Dated: October 20, 2003  
Received: October 21, 2003

Dear Ms. Thorson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

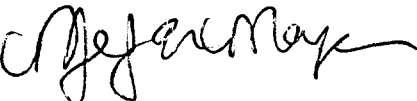
Page 2 – Ms. Diane M. Thorson

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

510(k) filed on October 10, 2003

Device Name: ApexPro FH Telemetry System

Indications For Use:

The ApexPro FH Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro FH Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K033365Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)